REMARKS/ARGUMENTS

In the specification, paragraphs on pages 3, 6, and 7 have been amended. The amendments are being made in order to ensure compliance of this application with United States patent practice, as the present application is based upon a foreign counterpart. The scope of the invention as embodied in the claims has not been altered.

FIGS. 1 and 2 of the drawings have been amended to properly designate them as prior art. Claim 30 has also been amended for a reason not relating to a statutory requirement for patentability discussed more fully below.

None of pending claims 1, 3-11, and 27-30 has been substantively amended, as each defines patentable subject matter in its present form.

Applicant's Invention

Applicant's invention is directed to a configuration for a stent adapted for placement in a body lumen, such as a blood vessel or urethra, among others. Among the phenomena with which the invention is concerned is that which may occur when a stent having a lattice structure is placed in a vessel having a small radius of curvature. When such a stent is placed in a curved vessel, portions of its lattice structure may project into the internal lumen of the stent in a manner that comprises the luminal cross-sectional area of the stent. (application 2:14-19). The projection of a portion of the stent into the lumen may be most pronounced on the inside, tighter radius of the vessel curve. Among the objectives of one aspect of applicant's invention is to avoid such obstruction of the stent lumen. This is desirable in blood vessels, for example, in that by avoiding the projection of portions of the lattice into the lumen, uncontrollable vortices in blood flowing in the vessel may be avoided. Vortices and turbulent blood flow can lead to vessel occlusion.

To this end, applicant's stent is formed of a lattice structure comprised of "wall segments" (18) which are said to "branch off" at intersections, some (22) of which are interrupted, and others (20) which are not. The wall segments at the interrupted intersections are preformed to have a relaxed, undeformed and resiliently expanded

state in which they project radially outward. As a result of the wall segments having a preformed radially outward projection, the stent is capable of being implanted in a vessel of strong curvature such that a reduction of the inner lumen is prevented. (3:1-5).

As acknowledged at page 4 in the application, the prior art discloses stents having interrupted portions adapted to enhance flexibility. (1:37-2:14). However, when the stent is curved, as when placed in a narrowly curved vessel zone, the edges of the disconnected, interrupted portions of the stent may project into the internal lumen of the stent, particularly at the inside of the curve. It is also known and acknowledged on page 2 of the application to provide a stent with barbs projecting in the direction of the vascular tissue in order to anchor a stent in a vessel. These barbs, however, do not change the basic lattice structure of the stent and do not prevent a reduction of the inner lumen of the stent. (2:30-35). In one aspect of applicant's invention, the occlusion of the lumen is avoided by preforming the stent to have a resiliently expanded, undeformed, configuration in which the wall segments, particularly those that meet at an interrupted intersection project radially outward at an angle to the longitudinal direction of the stent. This is illustrated in FIGS. 3 and 5 of the application and, more particularly, in enlarged FIG. 7 which shows applicant's stent placed in a sharply curved blood vessel. FIG. 7 illustrates the strut-like wall segments and the manner in which the ends of the wall segments are "expanded in the radial direction." Once placed in a curved blood vessel, the preformed radially outward orientation of the ends of the wall segment causes them to lie along the luminal surface of the vessel so that they do not project into the lumen defined through the stent.

FIG. 6 of the application illustrates a mold in which the configuration of a stent made in accordance with this aspect of applicant's invention is preformed to assure that the wall segments, particularly those at the interrupted intersections inclined radially outwardly.

The Cited Prior Art

U.S. Patent No. 5,514,154 (Lau)

The Lau patent is directed to a stent having a plurality of radially expandable cylindrical elements, each of which defines in a somewhat serpentine pattern. Adjacent hoop-like cylindrical elements are connected to each other by interconnecting elements 13. Some of the peaks defined by the serpentine configuration are not associated with interconnecting elements. Interconnecting elements 13 preferably connect a peak to a valley in the undulating structure. The serpentine pattern 30 is said to be made up of a plurality of U-shaped members 31, W-shaped members 32, and Y-shaped members 33.

The stent is formed from a cylindrical tube by chemical etching. As near as can be determined from Lau, all of the components of the stent, including the U-shaped, W-shaped and Y-shaped members lie in the cylindrical wall of the stent before the stent is expanded. Lau explains, however, that "during radial expansion U-shaped members 31 will tip outwardly thereby forming outwardly projecting edges... [that] provide for a roughened outer wall surface of stent 10 and assist in implanting the stent in the vascular wall by embedding into the vascular wall." (Lau 6:19-24). Lau also states that although "any of the U-shaped members 31, W-shaped members 32, and Y-shaped members 33 can tip radially outward to form a projecting edge 34 [, it] is **most likely** and preferred that U-shaped members 31 tip outwardly ...". (6:28-32) (emphasis supplied). Lau does not explain how any of the members 31, 32, or 33 are caused to tip outwardly. No special steps are suggested during the manufacture of the stent and no particular structure is disclosed other than the specific stent pattern. As near as may be determined from the Lau disclosure, the outward tipping characteristic that results when the stent is expanded appears to be an unexplained phenomenon that occurs with Lau's plastically expandable stent.

Lau is directed specifically to providing a stent with increased longitudinal flexibility during delivery of the stent, but is silent with regard to capability to be implanted in an area of strong curvature. Lau states, "What has been needed and heretofore unavailable is a stent which has a high degree of flexibility so that it can be

advanced through tortuous passageways and can be readily expanded and yet have the mechanical strength to hold open the body lumen into which [it] is expanded." (1:44-50). Lau is concerned with increasing a stent's longitudinal flexibility during delivery when the stent is in a radially compressed state, but is focused on providing a stent, "which is stiff and stable enough radially in an expanded condition...". (1:55-56). Lau shows the expanded stent only in a longitudinally non-flexed, or straight position. (See FIGS. 2, 3, and 13 of Lau).

European Patent Application 0 792 627 A2 (Fogarty)

Fogarty discloses a stent having a wall thickness between about 0.1 mm and 0.5 mm.

Rejections Under 35 U.S.C. §112

Although applicant traverses the rejection of claim 30 under 35 U.S.C. §112, it has been amended to correct a clerical error to properly identify its dependence on a **combination** in accordance with claim 27, and not a **process**. This amendment is cosmetic because the limitations of amended claim 30 are identical to those previously presented in the claim. There is no basis in the action to support the notion that one of ordinary skill in the art would not have understood the scope of the claim as is necessary to support the 35 U.S.C. §112 rejections. While the choice of language may not have been consistent, the inconsistency was not such that one of ordinary skill would not have understood the scope of the claim. The claim, although objectionable in its original form was not rejectable under section 112. The amendment corrects the objectionable form. Should the examiner disagree with this distinction and remain of the opinion that the appropriate way to deal with claim 30 was by section 112 rejection and not by objection, it is requested that applicant be so advised. Otherwise, applicant will assume that the examiner agrees with applicant's position.

Rejections Under 35 U.S.C. §102

Anticipation under 35 U.S.C. §102 requires each and every limitation of the claim

to be disclosed in a single prior art reference, either expressly or inherently. The anticipating reference must disclose the elements in the arrangement called for by the claim. If any limitation of the claim is missing, the reference does not anticipate.

Reconsideration is requested of the rejection of claims 1, 3, 8-10 and 27-29 as anticipated by Lau '154. Lau fails to disclose a stent as defined in claim 1 having wall segments that are "...preformed to have a relaxed, undeformed and resiliently expanded state in which they project radially outward". Lau does not disclose that the self-expanding stent has radially outwardly projectable wall segments that are independently radially self-expandable to an outwardly projecting configuration. In Lau, the stent is not elastically expandable from a compressed reduced diameter and those of its members 31, 32 or 33 that may, possibly, project outwardly, do not do so under the influence of their own resilience. Lau merely discloses that, "**after** cylindrical elements 12 have been radially expanded, outwardly projecting edges 34 are formed." (emphasis supplied). (Lau, 6:17-20).

Moreover, in Lau, the U-shaped members apparently are caused to tip outwardly only as a consequence of the balloon expansion of the stent, not by the stent being formed to have applicant's claimed "preformed", "radially expanded wall segments". In Lau, any outward tipping of any portion of the stent is a consequence, perhaps originally unintended, of the forceful radial and plastic expansion of the stent, not of any design characteristic, such as applicant's claimed preformed radially extending wall segments. Indeed, Lau appears to be less than certain as to the manner in which the device operates. Lau, at most, surmises that the U-shaped members 31 tip outwardly when the stent is expanded. "...it is ***most likely*** and preferred that U-shaped members 31 tip outwardly since they do not join with any connecting member 13 to prevent them from expanding outwardly." (6:30-33). (emphasis supplied).

In addition to Lau not disclosing this structural limitation, Lau also does not have the following functional limitation which flows from the recited structural limitation; that is, a stent having "...wall segments [that] are expanded in the radial direction...such that, upon curvature of the stent along the longitudinal direction, a reduction of the inner lumen due to the wall segments at the interrupted intersections is prevented." Although

Lau discloses a longitudinally flexible stent in which some portions of the undulating pattern of the stent "most likely" will "tip outwardly" to project outwardly from the outer surface of the stent to secure the stent to the vessel tissue, that is not the same as avoiding obstruction of the lumen of the stent when the stent is bent. This is a capability of the present invention and is embodied in the claimed features of the wall segments having the preformed radially outward projection which prevents reduction of the stent lumen at the intersections.

There is nothing in Lau that recognizes the problem of avoiding obstruction of the stent lumen when implanted in a curved vessel, and there is further, nothing in Lau to describe an intentional structure designed to reduce the incidence of that problem. It does not necessarily follow that the "outward tipping", which is only said to serve as a means for embedding the stent in the vascular wall to secure the stent in place, would prevent part of Lau's cylindrical member 12 from projecting into the lumen of the stent when the Lau stent is placed in a curved vessel.

Each of claims 3, 8-10 and 27-29 depends from claim 1 and is not anticipated for the same reasons. Additionally, as to claim 3, Lau does not disclose a stent structure with preformed wall segments having a relaxed, undeformed and resiliently expanded state in which they project radially outward wall segments, as such curvature allows the wall segments to elastically return to their relaxed state.

Rejections Under 35 U.S.C. §103

Reconsideration is requested of the rejection of claims 4, 5, 11 and 30 as defining subject matter that would have been obvious in view of Lau. Each of these claims depends either directly or indirectly from claim 1 and includes the same limitations discussed above. Lau fails to suggest that the stent has wall segments which are preformed to have a relaxed, undeformed and resiliently expanded state in which they project radially outward. Lau also fails to suggest the limitation of the stent having "wall segments that are expanded in the radially direction such that, upon curvature of the stent along the longitudinal direction, a reduction of the inner lumen due

to the wall segments at the interrupted intersections is prevented." In the absence of evidence to support the rejection, the rejection is improper and should be withdrawn.

As to limitations that the action acknowledges are not disclosed in Lau (stent wall intersections interrupted at substantially two-thirds of all intersections, aperture widths of maximally 9 mm when the stent is expanded, and alloy moieties as claimed), there is no evidence to support the supposition that the limitations are a "matter of design choice".

In cases where a single prior art reference is alleged to render the claimed invention obvious, there must be a sufficient showing of a suggestion or motivation for any modification of the teachings of that reference necessary to reach the claimed invention. *Sibia Neuroscis., Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.* 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996). This suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Sibia,* 225, F.3d at 1356, 55 USPQ2d at 1931; *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 60 USPQ2d 1001 (Fed. Cir. 2001).

Here, the action does not explain any reason for one to have been motivated to modify Lau so that the portions of the Lau stent would not project into the lumen defined by the stent when the stent is curved. With regard to claim 4, the action offers no evidence why the limitations regarding the wall segments being interrupted in regular distribution at substantially two-thirds of all intersections would merely be a "design choice" to one of skill in the art. The action also presents no evidence why the claimed limitations regarding the aperture widths of claim 5 and alloy moieties of claims 11 and 30 would be merely one of design choice to one of skill in the art. Such evidence is necessary to support a rejection under 35 U.S.C. §103. See *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999).

Claim 7 includes the same limitations of claim 1. Fogarty does not include those features of applicant's invention, discussed above that are missing from Lau. Reconsideration of the rejection of claim 7 is requested.

The application is considered to be in condition for allowance and such action is solicited.

Respectfully transmitted,

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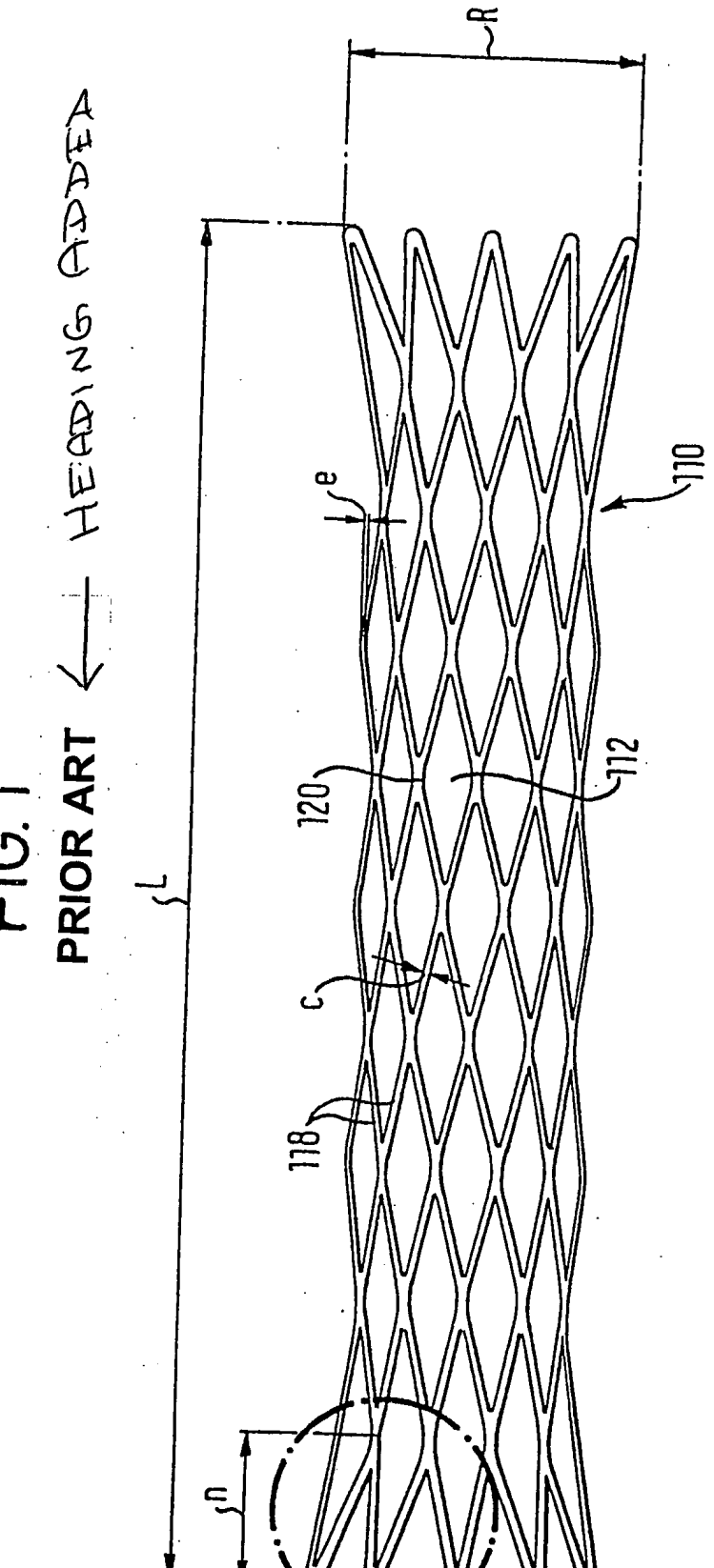

FIG. 1
PRIOR ART

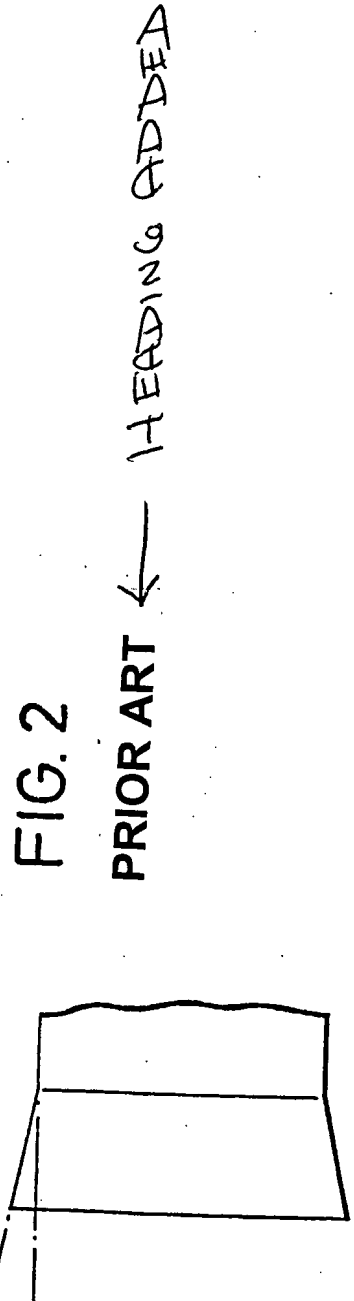

FIG. 2
PRIOR ART